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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,460	12/29/2005	Etienne Pouteau	112701-697	6141

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K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,460	POUTEAU ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 19 Aug 2009, in which claims 1, 3, 5 and 6 are amended to change the scope and breadth of the claim and new claims 7-12 are added.

This application is the national stage entry of PCT/EP04/07092, filed 30 Jun 2004; and claims benefit of foreign priority document EP 0301486.7, filed 30 Jun 2003. This foreign priority document is in English.

Claims 1 and 3-12 are pending and examined on the merits herein.

Rejections Withdrawn

Applicant's Amendment, filed 19 Aug 2009, with respect to claims 5 and 6 rejected under 35 U.S.C. 112, first paragraph as not being enabled for the full scope of the claim with regard to the patient treated has been fully considered and is persuasive, as amended claims 5 and 6 are enabled for the scope of the patient population treated.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 19 Aug 2009, with respect to claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as amended claims 1 and 5 definitely recite the improvement is reducing insulin resistance, amended claims 3 and 6 do not recite broad

and narrow ranges in the same claim, and amended claims 5 and 6 clearly recite the subject treated such that the one of skill in the art could determine what is meant by “effective amount".

This rejection has been **withdrawn**.

Applicant’s Amendment, filed 19 Aug 2009, with respect to claims 1 and 3-6 rejected under 35 U.S.C. 102(b) as being anticipated by Hoie (US Patent Application Publication 2003/0113390, published 19 Jun 2003, of record) has been fully considered and is persuasive, as Hoie does not disclose a method comprising administering lactulose.

This rejection has been **withdrawn**.

Applicant’s Amendment, filed 19 Aug 2009, with respect to claims 1, 3, 5 and 6 rejected under 35 U.S.C. 102(b) as being anticipated by Cashmere et al. (US Patent 4,921,877, issued 01 May 1990, of record) has been fully considered and is persuasive, as Cashmere et al. does not disclose a method comprising administering lactulose.

This rejection has been **withdrawn**.

Applicant’s Amendment, filed 19 Aug 2009, with respect to claims 1 and 3-6 rejected under 35 U.S.C. 102(b) as being anticipated by Hermansen et al. (US Patent Application Publication 2003/0060428, published 27 Mar 2003, of record) has been fully

considered and is persuasive, as Hermansen et al. does not disclose a method comprising administering lactulose.

This rejection has been **withdrawn**.

The following are new grounds of rejection necessitated by Applicant's Amendment, filed 19 Aug 2009, in which claims 1, 3, 5 and 6 are amended to change the scope and breadth of the claim and new claims 7-12 are added.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada et al. (US Patent Application Publication 2003/0181401, filed 3 Feb 2003,

cited in PTO-892) in view of Schumann (Eur. J. Nutr., 2002, 41 (Suppl 1), pI/17-I/25, cited in PTO-892) and in view of Spiller (CRC Handbook of Dietary Fiber in Human Nutrition, 2001, 3rd Ed, p373-400, cited in PTO-892).

Takada et al. teaches a method for suppressing elevation of a blood glucose level and a ameliorating diabetes mellitus comprising administering at least one member selected from the group including a di- or higher saccharide containing galactose to a patient in need thereof (abstract). Takada et al. teaches diabetes mellitus includes reduced tissue sensitivity to insulin (page 1, paragraph 3). Takada et al. teaches the active ingredient administered in a dose of from about 1 mg ro 1 g per kg bodyweight (page 4, paragraph 72). Takada et al. teaches the active ingredient administered in a composition wherein said active ingredient is 0.1 to 100% by weight of the composition (paragraph 76 spanning pages 4-5). Takada et al. teaches the active ingredient formulated into an embodiment such as a nutritious composition for infants such as powder milks comprising 5-30% by weight amino acids, 40% by weight or less lipids, 40-80% by weight saccharide, and 0.05 to 1% by weight artificial sweetener (page 5, paragraphs 79-80), providing guidance for optimizing the amount of active ingredient present in the composition.

Takada et al. does not specifically teach the method of reducing insulin resistance or wherein the active ingredient is lactulose (instant claim 1 and 5). Takada et al. does not specifically teach the method for increasing insulin sensitivity (instant claim 4).

Schumann teaches lactulose is a known disaccharide containing galactose (page 1/17). Schumann teaches lactulose is commonly added to products for babies such as formula milks (page 1/18, right column, paragraphs 1-2). Schumann teaches lactulose is known to reduce increase of blood glucose and suggests a reduced glucose and insulin response (page 1/21, left column, first full paragraph).

Spiller teaches high fiber diets are known to be used to treat diabetes (page 373). Spiller teaches high fiber diets have been shown to improve peripheral insulin sensitivity (top of page 375). Spiller teaches high fiber diets probably exert their effect on glycemic control by improving insulin sensitivity (page 375, paragraph 3). Spiller teaches lactulose is known to be a type of fiber used in said high fiber diets (table 5.3.1 at page 378). Spiller teaches a connection between high fiber diets reducing risk for developing diabetes and insulin resistance as a risk factor for development of diabetes (page 391, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Takada et al. in view of Schumann and in view of Spiller. One of ordinary skill in the art would have been motivated to combine Takada et al. in view of Schumann to select the active ingredient di- or higher saccharide containing galactose to be lactulose because Takada et al. teaches the active ingredient formulated into an embodiment such as a nutritious composition for infants such as powder milks and Schumann teaches lactulose is commonly added to products for babies such as formula milks, and Schumann teaches lactulose is known to reduce increase of blood glucose and suggests a reduced glucose and insulin response. It would have been obvious to

one of ordinary skill in the art to combine Takada et al. in view of Schumann and in view of Spiller to give a method for treating and/or improving insulin resistance by reducing insulin resistance because Spiller teaches high fiber diets probably exert their effect on glycemic control by improving insulin sensitivity and teaches lactulose is a type of fiber used in said high fiber diets. It would have been within the ordinary level of skill in the art to determine the optimum concentration and dosage of the active ingredient taught by Takada et al. because Takada et al. provides guidance for varying the concentration in the composition and the dosage administered. See also MPEP 2144.05 II.A.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623